Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class:	Gardasil® (Human Papilloma Virus Recombinant) Injection
Date:	April 4, 2007
Prepared for:	
Prepared by:	Missouri Medicaid

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of Gardasil® (human papilloma virus recombinant).

Why was this Issue Selected: Gardasil® is a non-infectious prophylactic vaccine indicated for the prevention of cervical cancer, precancerous or dysplastic lesions, and genital warts caused by human papilloma virus (HPV) Types 6, 11, 16, and 18. HPV is the most common sexually transmitted virus in the United States. Approximately 10,000 women are diagnosed with cervical cancer every year, and an average of 10 women die each day from the disease. Gardasil® is not intended to be used for treatment of active genital warts; cervical cancer; cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), or vaginal intraepithelial neoplasia (VaIN). This product has not been shown to protect against diseases due to non-vaccine HPV types. Gardasil® is a ready-to-use, three dose, intramuscular vaccine. Women who receive Gardasil® should continue to undergo cervical cancer screening per standard of care.

Program-specific information:

Drug	Dose	Cost per ml (WAC)
• Gardasil®	Single Dose Vial	*$241.50*
• Gardasil®	Syringe	*$241.50*

Setting & Population: Patients 11 to 26 years of age

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent**

☒ **Appropriate Indications** ☐

Data Sources:	☐ Only administrative databases	☒ Databases + Prescriber-supplied

Setting & Population

- Drug for review: Gardasil® (human papilloma virus recombinant)
- Age range: Patients 11 to 26 years of age
- Gender: Female

Approval Criteria

- Female
- Patients 11 to 26 years of age
- Dosing limitation – series of 3 injections given over 6 month period
    - First dose: elected date
    - Second dose: 2 months after first dose
    - Third dose: 6 months after first dose
- Administration outside of recommended age guidelines – subject to clinical consultant review

Denial Criteria

- Pregnancy
- Lack of approval criteria

References

1. Facts and Comparisons, p.1533aa – 1533ac; 2007.
2. USPDI, Micromedex, 2007.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2007.
4. Merck & Co., “Gardasil Product Submission”, Whitehouse Station, NJ, 08889; June 2006.